

K091143

5. 510(k) Summary

NOV - 2 2009

Contact: Justin Eggleton
Musculoskeletal Clinical & Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
202.552.5800

Device Trade Name: SEC VBR

Manufacturer: Innvotech Surgical, Inc.
150 North Hill Drive, Suite 1
Brisbane, CA 94005

Common Name: Spinal intervertebral body fixation orthosis

Classification: 21 CFR §888.3060

Class: II

Product Code: MQP

Indications For Use:

The Innvotech Surgical SEC VBR is intended for partial vertebral body replacement to aid in surgical correction and stabilization of the spine. The device is indicated for use in the thoracolumbar spine (T1 to L5) to replace or restore height a collapsed, damaged, diseased, or unstable portion of a vertebral body, excised as a result of tumor or trauma (i.e., fracture). It is indicated to achieve decompression of the spinal cord and neural tissues, and to restore the height of a collapsed or damaged vertebral body.

The Innvotech Surgical SEC VBR is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period. The Innvotech Surgical SEC VBR is always to be used with supplemental internal spinal fixation. Additionally, the Innvotech Surgical SEC VBR may be used with bone graft.

Device Description:

The SEC VBR acts as a spacer to maintain proper vertebral body spacing and angulation following partial corpectomy. The SEC VBR is manufactured from Ti6Al4V and stainless steel. The SEC VBR is for single level anterior spinal use from T1-L5.

Predicate Device(s):

The SEC VBR was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used.

Performance Standards:

Testing performed on this device indicates that the SEC VBR is substantially equivalent to predicate devices. ASTM F2077 performance standards were adhered to and all applicable requirements were met.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Innvotech Surgical, Inc.
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Regulatory Advisers, LLC
Mr. Justin Eggleton
Director, Spine Regulatory Affairs
1331 H Street, NW – 12th Floor
Washington, District of Columbia 20005

NOV - 2 2009

Re: K091743

Trade/Device Name: SEC VBR
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: October 27, 2009
Received: October 28, 2009

Dear Mr. Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance.. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K091743

Device Name: SEC VBR

The Innvo tec Surgical SEC VBR is intended for partial vertebral body replacement to aid in surgical correction and stabilization of the spine. The device is indicated for use in the thoracolumbar spine (T1 to L5) to replace or restore height a collapsed, damaged, diseased, or unstable portion of a vertebral body, excised as a result of tumor or trauma (i.e., fracture). It is indicated to achieve decompression of the spinal cord and neural tissues, and to restore the height of a collapsed or damaged vertebral body.

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Prescription Use AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091743

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